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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,858

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Sadanobu Shirai

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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,858	<b>Applicant(s)</b> SHIRAI ET AL.	
	<b>Examiner</b> HASAN S. AHMED	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of applicants' amendment and remarks, both filed on 1 April 2009.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 1 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

As amended, claim 1 recites the limitation "other than an acrylic adhesive." After carefully examining the instant disclosure, the examiner respectfully submits that support for this amendment is lacking and the addition of said limitation is new matter. Specifically, said limitation is not set forth in the instant specification. The specification, including page 5, lines 4-13, have been carefully reviewed and sufficient support for the limitation "other than an acrylic adhesive" was not found. While the instant specification indicates that acrylic adhesives are not preferred, there is no absolute exclusion indicated, as is currently claimed. According to the specification, "...the patch related to the present invention does not need such substances (i.e. acrylic adhesives)..." (see

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page 5, lines 9-10), however the specification does not recite that the adhesive resin must be other than an acrylic adhesive, as is currently claimed.

\* \* \* \* \*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No. 7,056,528 ("Bracht") in view of U.S. Patent No. 5,866,157 ("Higo").

Bracht teaches a transdermal therapeutic system comprising:

- 2.5-20% tulobuterol (see col. 3, line10);
- 2-20% of a C<sub>11-22</sub> fatty acid (see col. 4, lines 8-9);
- a rubber (styrene) (see col. 3, line 24);
- adhesive resin (tackifiers) (see col. 4, line 21); and
- plasticizer (see col. 4, line 21).

Bracht explains that the disclosed invention is beneficial in that it results in skin permeation of tulobuterol at rates sufficient to ensure therapeutic application (see col. 2, lines 32-34).

Bracht differs from the instant application in that it does not disclose concentrations of rubber, adhesive resin, or plasticizer, or the specific adhesive resins of instant claim 4.

Higo teach a percutaneous patch formulation (see col. 2, lines 32-39; Example 5). The disclosed patch is comprised of:

- an adhesive layer on a backing (see col. 6, line 7);
- said adhesive layer comprising:
  - 1-4% (w/w) tulobuterol (see col. 3, lines 39 and 58);
  - 0.01-20% (w/w) C<sub>11</sub>-C<sub>22</sub> fatty acids (see col. 4, line 60 – col. 5, line 32);
  - 15-60% (w/w) rubber (see col. 3, line 64 – col. 4, line 9);
  - 10-70% (w/w) adhesive resin (see col. 4, lines 19 - 37); and
  - 10-60% (w/w) plasticizer (see col. 4, lines 38 - 59).

Among the disclosed adhesives are alicyclic saturated hydrocarbon resins (see col. 4, line 26).

While Bracht and Higo do not explicitly teach all the instantly claimed percentages, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955).

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Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined tulobuterol, a rubber, an adhesive resin, a higher fatty acid, and a plasticizer into a patch formulation, as taught by Bracht in view of Higo. Motivation, as explained by Bracht, comes from the resulting skin permeation of tulobuterol at rates sufficient to ensure therapeutic application.

\* \* \* \* \*

### ***Response to Arguments***

Applicants' arguments filed 1 April 2009 have been fully considered but they are not persuasive.

1. Applicants argue that the Bracht preparation contains tulobuterol hydrochloride rather than tulobuterol. See page 4.

Examiner respectfully submits that the scope of claim 1, as currently constructed, does not preclude a salt form of tulobuterol, e.g. it does not recite a free base form of tulobuterol.

2. Applicants argue that a polyacrylate pressure-sensitive adhesive and a polymer having an amino-functional group in its side chains are essential ingredients of the Bracht preparation. See page 4.

As explained in the 35 USC 112 rejection above, the newly added limitation excluding acrylic adhesives is deemed to be new matter, as such an exclusion is not disclosed in the original specification.

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4. Applicants argue that Higo discloses an adhesive layer comprising an organic acid and an absorption enhancer, which is excluded by use of the transition phrase "consisting of". See pages 5-6.

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Higo was invoked only for the teachings of rubber, adhesive resin, and plasticizer concentrations as well as a teaching of one of the particular adhesive resins recited in instant claim 4.

Further, examiner respectfully submits that the scope of instant claim 1 is broad enough to encompass an adhesive layer comprising an organic acid and an absorption enhancer. For example, Higo discloses an organic acid such glycol salicylate to be a plasticizer. Further, higher fatty acids are disclosed by Higo to function as absorption enhancers (see col. 4, line 64).

\* \* \* \* \*

### **Conclusion**

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1615

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615